

### REMARKS

Claims 19 to 34 are in the application. Claim 19 has been amended to correct a typographical error. No new matter is believed added.

Applicants gratefully acknowledge the withdrawal of the rejection to the claims as listed in the Office Action, pages 2 and 3, paragraphs 3 and 4.

Applicants also amend the specification to include a paragraph of information which appears in US Patents No. 6,372,253 and US 6,350,469 column 3, lines 11 to 28 and lines 5 to 22 respectively. Applicants specification, page 7, last paragraph provides express support for the incorporation by reference material. No new matter is believed added.

#### Rejection under 35 USC §112, second paragraph

Claims 19-34 are rejected under 35 USC §112, 2<sup>nd</sup> paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

Claims 18 and 27 are indefinite as stated by the Examiner as “they contain the recitation of “methylcellulose having a viscosity of 4000 centipoise” without setting forth the conditions under which viscosity is measured”. Claim 18 has been cancelled previously. Presumably the Examiner actually means Claims 19 (and 27) as being rejected under 112, 2nd paragraph. Applicants will respond accordingly based upon this correction.

While viscosity testing may, or may not, be determined under different temperatures and conditions, this is not considered relevant to the particular point in question herein. As clearly identified in US 6,37,253 and US 6,350,469 column 3, lines 11 to 28 and line 5 to 22 respectively, the apparent viscosity of methylcellulose is determined under USP/NF conditions in a particular manner. A copy of the monograph accompanies this response for the Examiner’s review. The monograph actually appears on page 864, not page 894 as indicated in the ’53 and ’469 patents. The methylcellulose products are sold in the marketplace based upon the viscosity of the product, as further noted in the above patents. The manufacturers of these materials clearly define and provide extensive information on the cellulose ethers and

their preparation. This is not a term which is indefinite by any means for this particular product.

Reconsideration and withdrawal of the rejection to the claims under 35 USC §112, second paragraph is respectfully requested.

Claims 19 to 34 are rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement.

The Examiner states that this is a “new matter” rejection. “The bases for this rejection is that the specification fails to support claims for methods of treatment consisting essentially of administering methylcellulose having a viscosity of 4000 centipoise.” Applicants respectfully disagree with this rejection.

As the Examiner has noted Applicants on page 7, lines 33 to 36 incorporated by reference two PCT application which have since become US patents US 6,37,253 and US 6,350,469. The paragraph while discussing alternative formulations of the methylcellulose including but not limited to the methylcellulose tablets disclosed in these patents, also indicates that the patents are incorporated by reference not solely for the tablet disclosure but “in their entirety” (page 7, line 36). Consequently, the discussion on viscosity is as though it were present in this application as filed.

The MPEP discusses incorporation by reference at section 2163.07(b): Incorporation by Reference as shown below. The relevant clauses being underlined.

“Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See 37 CFR 1.57 and MPEP § 608.01(p) for Office policy regarding incorporation by reference. See MPEP § 2181 for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.”

The relevant sections of 37 CFR 1.57 are also shown below:

(c) "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material" is material that is necessary to:

(1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;

(2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or

(3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

(d) Other material ("Nonessential material") may be incorporated by reference to U.S. patents, U.S. patent application publications, foreign patents, foreign published applications, prior and concurrently filed commonly owned U.S. applications, or non-patent publications. An incorporation by reference by hyperlink or other form of browser executable code is not permitted.

While the Examiner has not commented upon whether an amendment to the specification incorporating the particulars of the viscosity discussion are essential or not, Applicants have amended the application accordingly. Following the requirements of the 37 CFR 1.57 (f), Applicants state that "the material being inserted is the material previously incorporated by reference and that this amendment contains no new matter."

Consequently, it is believed that this should remove the Examiner's rejection to the claims under 35 USC §112, first paragraph.

#### Rejection under 35 USC §112, first paragraph

Claims 19 to 34 are rejected under 35 USC §112, first paragraph as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection as well.

The Examiner's comment for this rejection is "that one of skill in the art cannot use the specification to make or use the claimed invention without undue

experimentation". The Examiner further cites various factors to be considered in determining undue experimentation on page 5 of the office action, 2<sup>nd</sup> full paragraph. In addition the Examiner cited a later publication of Baron, 2005 which is 6 years later than the filing date of this application against the claims. This is not prior art to the instant application, and is therefore not a valid use against the claims herein. There are additional studies on the use of methylcellulose in this field, later published by Applicants which the Examiner also does not include. These are Davis PA, Yokoyama WH, Daggy BP (1999), Effect of soluble non-fermentable fiber and wheat bran on aberrant crypt foci (ACF) in a chemically induced rat model of carcinogenesis. *Gastroenterology* 116(4): A545. See also, Yokoyama WH, Knuckles BE, Davis PA, and Daggy BP (2002). Stability of ingested methylcellulose in the rat determined by polymer molar mass measurements by light scattering. *J Agric Food Chem* 50(26): 7726-7730. Copies of both of these articles accompany this response.

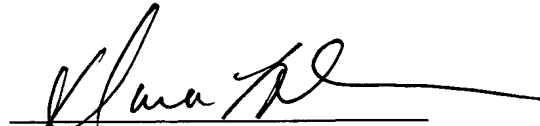
It should be noted that when reviewing any articles, researchers often mischaracterize methylcellulose. Methylcellulose is essentially a pure non-fermentable fiber, while wheat bran is subject to very limited fermentation and is not considered to be a pure fiber. Evidence has been presented in later publications which state that the protective effect of wheat bran is not necessarily due to its fiber content at all.

Secondly, the Examiner discusses the use of psyllium as being extrapolated to use in humans, page 5, last sentences of the 3<sup>rd</sup> paragraph, and comments that the specification lacks reasoning to do so. This is not what the data in the specification presents. On page 5, lines 29 to 36, continuing on page 6, lines 1 to 12, an actual experiment is presented using methylcellulose. All 3 combinations of administration (with methylcellulose) yielded fewer aberrant crypt foci. Consequently, applicants have indeed provided sufficient nexus to the claimed invention herein. There is no undue burden on the part of the skilled artisan to make and use Applicants claimed invention. Applicants have used an art recognized model and provided data in such model. Therefore, reconsideration and withdrawal of the rejection to the claims for lack of enablement is respectfully requested.

It is further noted that Applicants expressly requested that the Examiner grant Applicants an interview if the application was not going to be allowed upon the filing of this RCE. Applicants had not received a phone call and now request that the Examiner in fact make themselves available for such an interview. The Examiner is requested to contact the undersigned at the number indicated below upon receipt of this response to set up an appropriate time for discussion.

Should the Examiner have any additional questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Dara L. Dinner', is written over a horizontal line.

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